

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

(12) UK Patent Application (19) GB (11) 2 338 420 (13) A

(43) Date of A Publication 22.12.1999

(21) Application No 9914080.8

(22) Date of Filing 16.06.1999

(30) Priority Data

(31) 330754

(32) 19.06.1998

(33) NZ

(71) Applicant(s)

Fisher & Paykel Limited
(Incorporated in New Zealand)
78 Springs Road, East Tamaki, Auckland,
New Zealand

(72) Inventor(s)

Hayden Bradley Foot

(74) Agent and/or Address for Service

Forrester Kettle & Co
Forrester House, 52 Bounds Green Road, LONDON,
N11 2EY, United Kingdom

(51) INT CL⁶

A61M 16/16

(52) UK CL (Edition Q)

A5T TDB

(56) Documents Cited

EP 0845277 A1 US 5349946 A US 5163423 A

(58) Field of Search

UK CL (Edition Q) A5T TDB

INT CL⁶ A61M 16/16

ONLINE:WPI,EPDOC,JAPIO

(54) Abstract Title

Humidified sleep apnea treatment apparatus

(57) Apparatus and method of treating OSA (Obstructive Sleep Apnea) are disclosed wherein a Positive Airway Pressure device is utilised to provide a gases supply which is then passed through a humidifier. As the amount of water vapour generated by the humidifier is very low at start up (typically the humidifier comprises a water container on a heating plate) the pressure of gases supplied by the apparatus are controlled so that the required pressure and resulting flow rate is reached at the same time as the required humidity level is reached. A control strategy is disclosed where the pressure is incrementally adjusted to keep pace with the increases in humidity. By means of a controller 9 which adjusts the speed of fan 21 in response to the humidity level which is estimated on the basis of temperature.

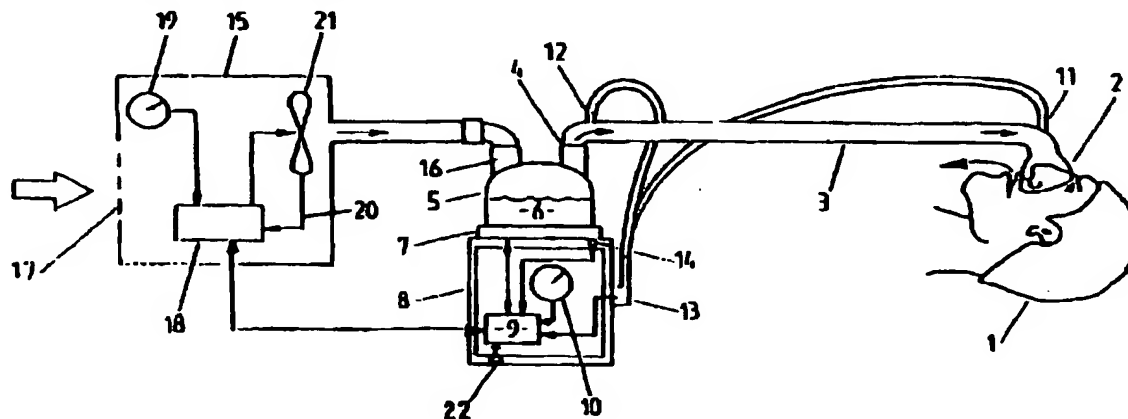


FIG. 1

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995

GB 2 338 420 A

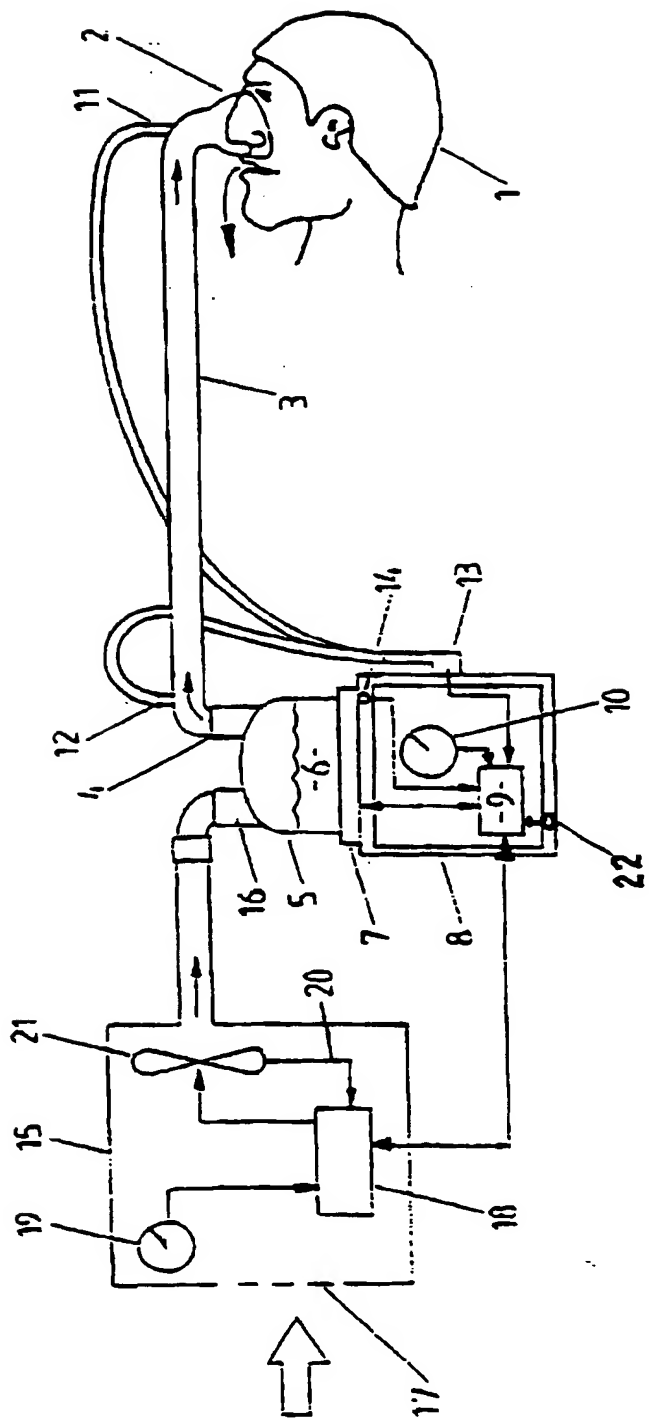


FIG. 1

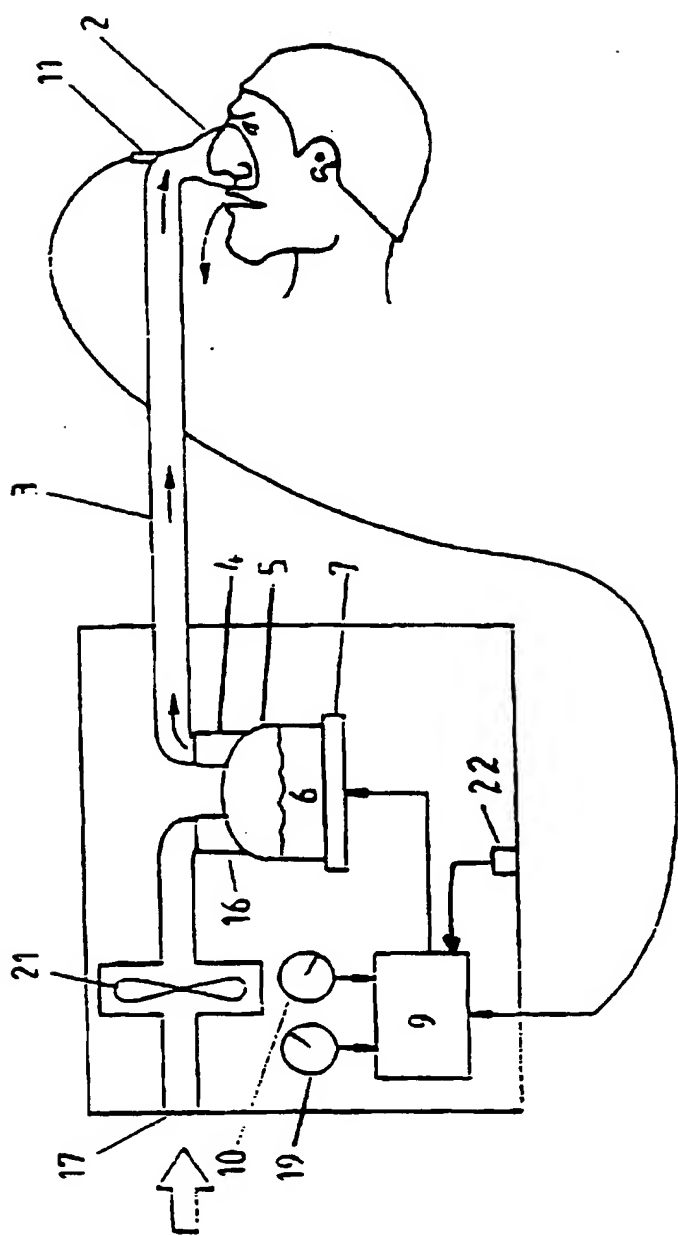
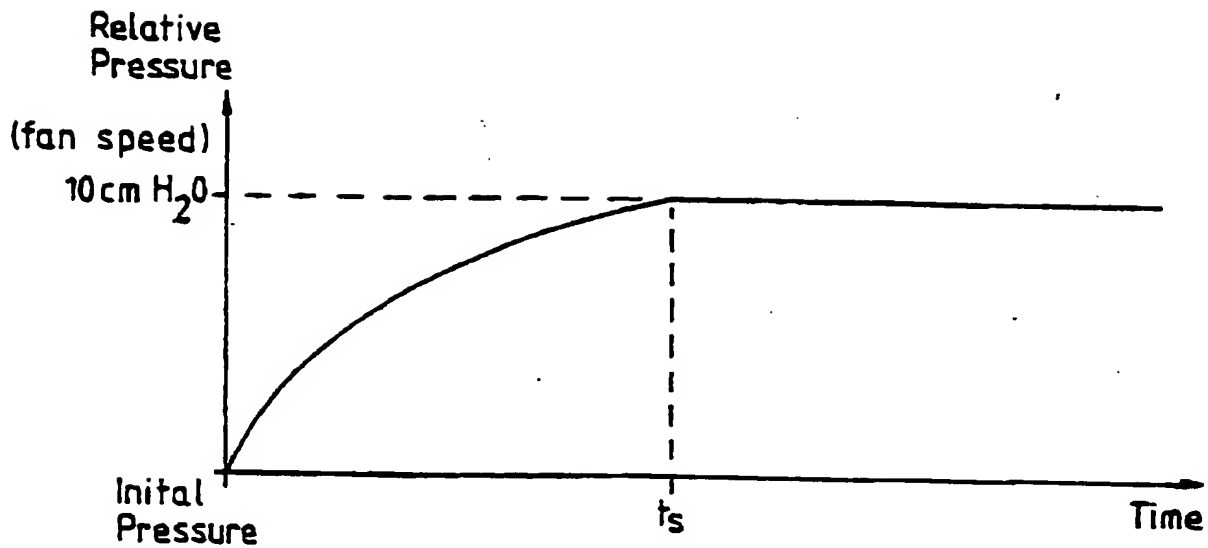
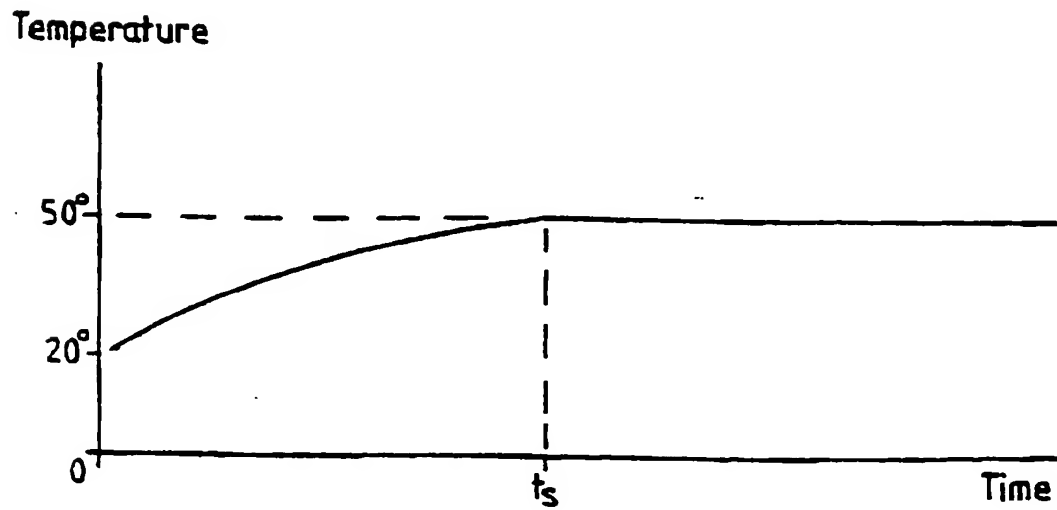


FIG. 2

FIG. 3FIG. 4

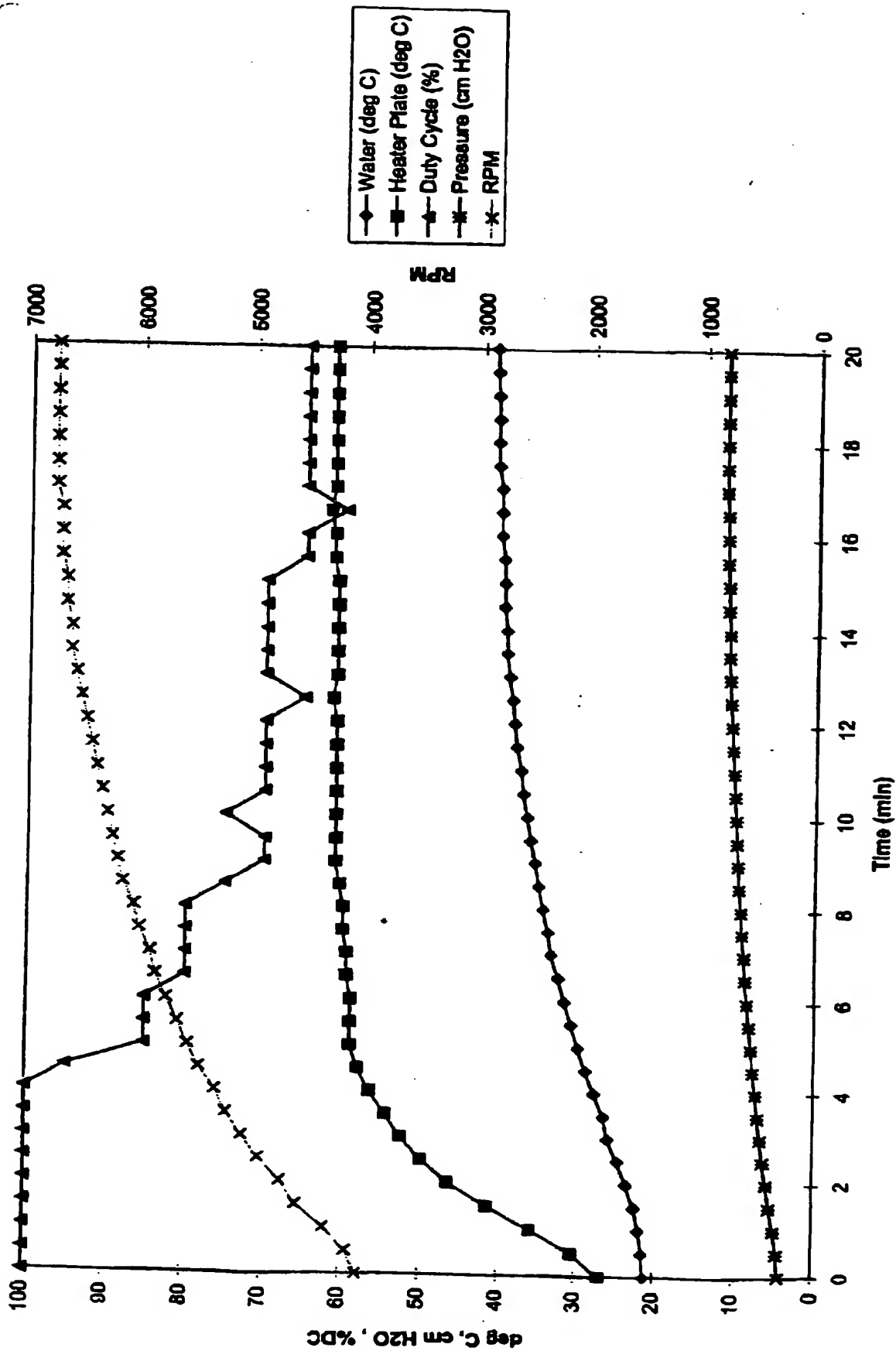


Figure 5

This invention relates to health care apparatus and in particular, though not solely to humidified Positive Airway Pressure (PAP) apparatus used in the treatment of Obstructive Sleep Apnea (OSA) and a method of controlling such apparatus.

OSA is a sleep disorder which affects an estimated least 5% of the population in which muscles which normally hold the airway open, relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The use of a CPAP system is known to have side effects such as dehydration of the airways and nasal passages which may lead to Rhinitis (inflammation of the nasal passages). The side effects mean that the patient is less likely to comply with his or her CPAP therapy and the therapy itself may cause an increase in nasal resistance as a response to the high air flow, degrading the pressure level applied to the airway and thereby reducing the effectiveness of the therapy. Accordingly, a humidified CPAP system would be an improvement. An improvement on the standard CPAP system is described in US patent No. 5,537,997 assigned to Respironics Inc. in which a humidifier is incorporated with the CPAP system so that the patient receives humidified gases.

However, a mere combination of a well known humidifier (in which gases are passed through water vapour rising from the surface of water in a water humidification chamber on top of a heater plate) and a CPAP device would not maximise the benefit of the humidified CPAP therapy to the patient. This is due to the heater plate taking some time to warm up so that the patient would, on some occasions (especially during warm-up of the apparatus), be supplied with gases which were not humidified. It should be noted that the sensitive tissues of the nasal passage can be caused to swell after

receiving only as little as 10 minutes of non-humidified gases flow. Accordingly, it would be an advantage if the gases received by the patient were always humidified (to the present or existing capability of the humidifier) at any point in time.

5 It is therefore an object of the present invention to provide breathing assistance apparatus which will go at least some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

Accordingly, in a first aspect, the invention consists in breathing assistance apparatus adapted to deliver gases to a patient to assist said patient's breathing comprising:

10 gases supply means, including pressure regulating means adapted to supply gases at a required pressure with a resulting gases flow rate,

gases pressure sensing means to determine the pressure of said supplied gases and thereby the resulting gases flow rate,

15 humidification means which receive and humidify said supplied gases prior to delivery to said patient, said humidification means capable of controllably humidifying said gases up to a required humidity level,

transportation pathway means which convey said humidified gases to said patient,

20 gases humidity sensing means to determine the humidity of the gases supplied to said patient, and

25 control means which in response to said gases humidity and said gases flow rate information supplied by said gases humidity sensing means and said gases pressure sensing means, controls said gases supply means such that said gases pressure reaches said required pressure at substantially the same time as said required humidity level is reached.

30 In a second aspect, the invention consists in a method of operating patient breathing assistance apparatus, said breathing assistance apparatus comprising gases supply means, gases pressure regulating means adapted to supply gases at a required pressure with a resulting gases flow rate, gases humidification means capable of controllably humidifying said gases up to a required humidity level, transportation means which convey said humidified gases to said patient and control means storing

predetermined required pressure and humidity values, said method comprising the steps of:

a) initiating said gases humidification means to humidify the gases from said gases supply means,

5 b) sensing the pressure of said gases,

c) sensing the humidity of said gases, and

d) controlling the pressure at which said gases are supplied to said patient so that said gases pressure and resultant flow rate reaches said required pressure and resultant flow rate at substantially the same time as said required humidity level is reached.

10 In a third aspect, the invention consists in a method for treating Obstructive Sleep Apnea in a patient using a breathing assistance apparatus comprising gases supply means, gases pressure regulating means adapted to supply gases at a required pressure with a resulting gases flow rate, gases humidification means capable of controllably humidifying said gases up to a required humidity level, transportation means which
15 convey said humidified gases to said patient and control means storing predetermined required pressure and humidity values, said method comprising the steps of:

a) initiating said gases humidification means to humidify the gases from said gases supply means,

b) sensing the pressure of said gases,

20 c) sensing the humidity of said gases, and

d) controlling the pressure at which said gases are supplied to said patient so that said gases pressure and resultant flow rate reaches said required pressure and resultant flow rate at substantially the same time as said required humidity level is reached.

25 One preferred form of the invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram of a humidified Continuous Positive Airway Pressure (CPAP) system in accordance with a preferred embodiment of the present invention,

Figure 2 is a block diagram of a humidified CPAP system in accordance with a further preferred embodiment of the present invention,

30 Figure 3 is an example graph of air pressure (approximated by fan speed) versus time for the humidified CPAP system according to the first preferred embodiment of

th present invention,

Figure 4 is an example (corresponding to Figure 3) graph of humidity (actually heater plate temperature) versus time for the humidified CPAP system according to the second preferred embodiment of the present invention, and

5 Figure 5 is a graph of experimentally collected data versus time for a number of parameters in the humidified CPAP system according to the second preferred embodiment of the present invention.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised
10 gases through a nasal mask 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that the present invention, however, is not limited to the delivery of CPAP gases but is also applicable to other types of gases delivery systems such as VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure). Inspiratory conduit 3 is connected to the outlet 4 of a
15 humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to ensure a constant humidity profile along the conduit and therefore reduce condensation of humidified gases within the conduit. Humidification chamber 5 is preferably formed from a plastics material and may have a highly heat conductive base
20 (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10
25 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources, for example temperature, humidity and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input
30 via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the

volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. It should be noted that it is possible to obtain the relationship between the humidity of the gases in humidification chamber 5 and the temperature of the heater plate 7. Accordingly, it is possible to utilise the heater plate temperature in an algorithm or a look-up table to determine the humidity of the gases (accordingly, the heater plate temperature acts as an indication of the humidity of the gases and the two terms are used interchangeably in this specification). Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1. It should also be noted that in the preferred form of the present invention, heater plate temperature is utilised to represent humidity, however, any suitable humidity sensor could alternatively be used.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17 producing a resultant gases flow rate. The speed of variable speed fan 21 is controlled by a further control means or electronic controller 18 (or alternatively the function of controller 18 could be carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of flow rate or pressure or fan speed (as has been mentioned above in relation to heater plate temperature and humidity, it is also possible to determine a relationship between fan speed, gases flow rate and gases pressure and the three terms are therefore used interchangeably in this specification) via dial 19.

An alternative preferred embodiment of a humidified CPAP system is shown in Figure 2 where the humidifier has been incorporated within blower 15 so that the system comprises only one main component connected to the patient via the same conduit 3 and nose mask 2. Only one controller 9 is required in this embodiment. This humidified CPAP system may be substituted into any of the preceding description including both "Warm-Up" mode embodiments. All reference numerals common to Figure 1 represent the same features of the invention.

It is possible to control the way in which the heater plate and/or the blower fan

is energised during "warm-up" (any time during which the heater plate has not reached its set or required temperature). The following are two preferred examples of control methodologies utilised in this period.

5 One Preferred "Warm-Up" Mode Embodiment

10 In use, a user of the humidified CPAP system determines a "set" (or required) value of gases pressure (P_{set}) to be delivered by blower 15 to the patient 1. This set value is passed to controller 18 by dial 19. The user also determines a "set" (or required) value of temperature (T_{set}) for the heater plate 7 which is entered to controller 9 via dial 10. The set temperature user input dial may be labelled "Humidity" for the user's convenience. Controller 9 then determines the present temperature of heater plate 7 (T_{actual}) through sensor 14 and the present gases pressure (P_{actual}), for example, from speed sensor 20. It should be noted that it could take up to 30 minutes for the gases to reach their set humidity level, depending upon ambient conditions, flow rates and any obstructions in the patient's airway (for example inflammation). The present pressure value may be determined by a pressure or flow sensor within blower 15, humidification chamber 5 or the conduits connecting the system or, alternatively, as has already been mentioned the speed of fan 21 (sensed by speed sensor 20 or alternatively the command speed issued to the fan by controller 18 may be utilised as the actual fan speed) may be used to represent the gases pressure.

20 Controller 9 then utilises the set and actual values of temperature (representing humidity) and pressure (or fan speed) to control the humidification and pressure of the gases flow to patient 1. The pressure and temperature (humidity) of the gases supplied to the patient will eventually be allowed to reach their values set by the user, however, to ensure that the patient is always supplied with humidified gases which have been saturated with the maximum possible amount of water vapour (within the presently existing limits of the humidifier), controller 9 controls the speed of fan 21 in step with the humidity of the gases (or in step with the temperature of the heater plate 7). As an example (with reference to Figures 3 and 4), the following table sets out the sensed (initial) and set (or required) temperature and (relative) pressure (equating to fan speed)

values at start up of the system.

| | Temperature | Pressure |
|---------|-------------|----------------------|
| Initial | 20°C | 0cmH ₂ O |
| Set | 50°C | 10cmH ₂ O |

Controller 9 then determines the required change in pressure (ΔP) and the required change in temperature (ΔT) to obtain the required set pressure and temperature respectively of the system. In the present case:

| | |
|-------------------------------------|-------------------------------|
| $\Delta P = 10\text{cmH}_2\text{O}$ | $\Delta T = 30^\circ\text{C}$ |
|-------------------------------------|-------------------------------|

Controller 9 then determines the required average rate of increase of pressure with respect to temperature by dividing ΔP by ΔT . In the present case this calculation equates to $10\text{cmH}_2\text{O}/30^\circ\text{C}$ or $\frac{1}{3}\text{cmH}_2\text{O}$ per $^\circ\text{C}$.

Accordingly, for each 1°C increase in heater plate 7 temperature, controller 9 will instruct controller 18 to increase the speed of fan 21 to achieve $\frac{1}{3}\text{cmH}_2\text{O}$ increase in pressure in this example. In this way, both the temperature and pressure of the gases supplied to the patient will reach their set values at the same time (that is at time t_1 in Figures 3 and 4). Preferably the heater plate will be energised upon initiation of the humidified CPAP system and will gradually increase in temperature up to its set temperature (as shown in Figure 4) at which time controller 9 will continuously suitably de-energise the heater plate and then re-energise the heater plate to maintain the set temperature. It should be noted that controller 9 could either continually monitor the heater plate temperature until the set temperature is reached and continually determine updated required average rate of increase values or the initially determined required average rate of increase could be used through the entire warm-up period. In this way the patient will only ever receive humidified gases because at start up, what little water vapour is present in humidification chamber 5 will be carried by a light gases flow while when the heater plate reaches its required set value (and therefore much more water vapour is being generated in the humidification chamber) the blower will be controlled to generate a larger volume flow rate of gases.

A Second Preferred "Warm-Up" Mode Embodiment

It should be noted that all integers shown and described in relation to Figures 1 and 2 are relevant to this second embodiment.

5 As in the previous preferred embodiment, the Humidified CPAP system according to this preferred embodiment has a "Warm Up" function which determines the way in which the motor speed (and hence delivered flow rate or pressure) of fan 21 increases with time after the device has been turned on. Hence it is desirable to increase the pressure and thereby the resultant flow rate as the humidity increases and therefore reach the desired set pressure as the humidity output of the device reaches its equilibrium or required level.

10 Controller 9 uses closed loop control of heater plate 7 temperature to reach the desired humidity level as soon as possible. Trials have indicated that the heater plate temperature alone (as used in the previous embodiment) is not necessarily a very good indicator of patient delivered humidity and that a much better indicator of humidity is the temperature of water in humidification chamber 5. It should also be noted that the water temperature increase is much slower than that of heater plate 7 because water is fairly poor at transferring energy. So controlling the fan speed based only upon heater plate temperature can lead to excessive flow rates too quickly in the warm up cycle. Although the water temperature is not measured directly (it would be impractical though not impossible to include a temperature sensor inside humidification chamber 5), it is possible to reasonably accurately estimate how the temperature of the water in humidification chamber 5 is increasing as will be described below.

15 The Specific Heat Capacity of water describes the amount of heat (or energy) that is required to increase a unit mass of water by one degree. Upon turn on of the humidified CPAP machine according to this preferred embodiment of the present invention, the controller 9 measures the actual temperature of heater plate 7 (assumed equal to water temperature in a steady state) and also receives input of the heater plate set (or required) temperature from a user (via a user interface including buttons, switches or dials for example). Controller 9 then determines the required change in temperature to reach the set (or required) humidity value. Preferably, controller 9 uses

90% of the required change in temperature as the water temperature in humidification chamber 5 only ever reaches 90% of the value of heater plate 7 set temperature at steady state conditions. Using the required change in temperature value (or a percentage of it) and knowing the mass of water in the chamber (assuming that the humidification chamber 5 is full with 400 ml of water equating to a mass of 400 g), the amount of energy required to increase the water to set temperature, can be calculated.

As controller 9 also controls energisation of heater plate 7, for example by controlling the duty cycle ($\text{time}_{\text{on}}/(\text{time}_{\text{on}} + \text{time}_{\text{off}})$) of the element, the amount of energy being transferred to the water by heater plate 7 is known. For example, for a 85 Watt heater plate element at a duty cycle of 60%, 51 Joules of energy are being transferred to the water every second. Energy is being taken out of the water by two dominant means being conduction and convection.

Conduction losses are transferred through the chamber walls and conduit. During warmup and at steady state, the amount of energy lost through conduction losses is directly proportional to the temperature gradient between the water and ambient (air temperature). Knowing the temperature of the water and the ambient air temperature (via, for example an ambient air temperature sensor 22 or more preferably by estimating a fixed temperature of say 20°C), the conduction energy losses (E_{cond}) can be estimated during warmup. In this embodiment, the water temperature is not directly measured, however, trials have indicated during warmup, the difference between the average water temperature and ambient is about 68% of the difference between the heater plate temperature and ambient, that is, $(T_{\text{water}} - T_{\text{ambient}}) = 0.68 \times (T_{\text{heater}} - T_{\text{ambient}})$. This approximation of water temperature has been found by sampling the heater plate and water temperature over the warm up period, dividing the water temperature by the heater plate temperature and then averaging the resulting values over the warm up period of time (from start-up until the gases are delivered at their required humidity).

Convection losses are due to air flow across the water in the humidification chamber 5. For the average flow of a CPAP user, the flow rate (Q) in litres per minute is directly proportional to the speed (v) of fan motor 21 in revolutions per minute (RPM) for a given restriction (assuming, for example a standard conduit of 6 foot

length) and that convection losses are approximately directly proportional to the flow rate. From experimentation the appropriate constants of proportionality have been determined and these are incorporated into the equations below. Therefore the convection energy losses (E_{conv}) can be estimated. Accordingly, at any point in time the net amount of energy being transferred (E_{trans}) to the water in humidification chamber 5 can be calculated.

In use, (and with reference to Figure 5) the warm-up algorithm according to the second preferred embodiment of the present invention works as follows:

A Ignoring Losses

1. Upon turn on of the humidified CPAP device, controller 9 reads the required or set fan speed and temperature (representing gases pressure and humidity) from user inputs 19 and 10 respectively and also the present temperature (T_{start}) of heater plate 7 - remembering that the water temperature is approximately 90% of that of the heater plate 7. Fan 21 is energised at an initial low speed of, for example, 3000 RPM, to create an initial pressure and resultant flow rate of, for example, 16 litres per minute (it is assumed that the flow rate (Q), in litres per minute, is directly proportional to fan motor speed (v) in RPM in a CPAP system such that $Q = v/186.2$). The amount of energy required ($E_{required}$) to increase the temperature of the mass (m) of water within humidification chamber 5 by an amount ($\Delta T = (T_{required} - T_{start}) \times 0.9$) to its set temperature is then calculated as follows (where k_s is the specific heat capacity of water):

$$E_{total\ required} = k_s \times m \times \Delta T = 4.19 \times 10^3 \times 0.4 \times (T_{required} - T_{start}) \times 0.9$$

Controller 9 then energises heater plate 7 in such a way (for example a closed loop control system adjusting the duty cycle of voltage applied to the heater element) that a predetermined required heater plate temperature (for example, approximately 60°C) is achieved as soon as possible with minimal or no overshoot.

2. At predetermined intervals of time (t_p), for example every 30 seconds, the net amount of energy ($E_{\text{transferred}}$) that has been transferred to the water in that interval from the heater element 7 (having a power rating of P_r Watts and with a duty cycle of D (%)) is calculated.

5

$$E_{\text{transferred}} = P_r \times t_p \times D$$

$$E_{\text{transferred}} = 85 \times 30 \times D = 2550 \times D \text{ [for a 30 second period]}$$

10

This value is then subtracted from the total required energy to heat the water to set temperature, giving the energy needed (from this point in time) to reach the set temperature. Thus initially:

15

$$E_{\text{needed}(\text{start})} = E_{\text{total required}} - E_{\text{transferred}} = 4.19 \times 10^3 \times 0.4 \times (T_{\text{required}} - T_{\text{start}}) \times 0.9 - (2550 \times D)$$

and more generally for each following iteration (i):

$$E_{\text{needed}(i)} = E_{\text{needed}(i-1)} - (2550 \times D)$$

20

3. Using the net energy transferred to the water over the last 30 seconds or rather, the average rate of net energy transfer (P_{transfer}), and the newly calculated value for the energy needed to reach the set temperature, an estimated time (t_s) to reach set temperature can be calculated as follows:

25

$$P_{\text{transfer}} = E_{\text{transferred}}/30 \text{ [in Watts]}$$

and

$$t_s = E_{\text{needed}}/P_{\text{transfer}}$$

30

therefore initially

$$t_s = (30 \times E_{\text{needed}(\text{total})}) / E_{\text{transferred}} \text{ [in seconds]}$$

and for following iterations an updated estimated time ($t_{s(i)}$) can be calculated as follows:

5

$$t_{s(i)} = (30 \times (E_{\text{needed}(i-1)} - E_{\text{transferred}(i)})) / E_{\text{transferred}(i)} \text{ [in seconds]}$$

B Including Losses

But, as previously mentioned, the amount of energy lost to the water within the humidification chamber through conduction and convection losses must also be accounted for. The conduction and convection losses may be calculated as follows:

10

$$E_{\text{conv}} = k_{\text{conv}} \times Q \text{ AND } Q = k_Q \times v$$

therefore

15

$$E_{\text{conv}} = k_{\text{conv}} \times k_Q \times v = (1/186.2) \times 5.79 \times v \text{ [for a 30 second period]}$$

also

20

$$E_{\text{cond}} = k_{\text{cond}} \times (T_{\text{water}} - T_{\text{ambient}}) = 10.83 \times 0.68 \times (T_{\text{heater}} - 20) = 7.4 \times T_{\text{heater}} - 148$$

[in Joules for a 30 second period during warmup]

the losses are added to E_{needed} and subtracted from $E_{\text{transferred}}$, accordingly

25

$$E_{\text{needed}(\text{actual})} = E_{\text{needed}(i-1)} - E_{\text{transferred}(i)} + E_{\text{conv}(i)} + E_{\text{cond}(i)}$$

$$E_{\text{transferred}(\text{actual})} = E_{\text{transferred}(i)} - E_{\text{conv}(i)} - E_{\text{cond}(i)}$$

and thus

30

$$t_{s(i)} = \frac{(30 \times (E_{needed(i-1)} - E_{transferred(i)} + E_{conv(i)} + E_{cond(i)}))}{(E_{transferred(i-1)} - E_{conv(i)} - E_{cond(i)})}$$

or alternatively:

$$t_{s(i)} = \frac{(30 \times (E_{needed(i-1)} - (2550 \times D) + ((1/186.2) \times 5.79 \times v) + (7.4 \times T_{heater} - 148)))}{((2550 \times D) - ((1/186.2) \times 5.79 \times v) - (7.4 \times T_{heater} - 148))}$$

- 10 4. Using this calculated time and the difference between set speed and actual speed an average rate of speed increase (γ) can be calculated:

$$\gamma = (v_{required} - v_{actual(i)})/t_{s(i)} \text{ [in RPM per second]}$$

- 15 The actual speed of the motor will then be adjusted accordingly to produce the calculated acceleration.

- 20 5. Steps 2 through 4 are repeated every 30 seconds (wherein the value of $E_{total\ required}$ is reduced by the net amount of energy transferred, $E_{transferred}$, to the water in the previous 30 seconds) causing the time to reach the set temperature and average required increase in motor speed to be continually calculated as the rate of net energy transfer to the humidification chamber changes. This step is repeated until the time to reach set temperature (t_s) is zero and set speed is reached, at which time the temperature of water within humidification chamber 5 should reach its required or set temperature also.

30 It should be noted that the above described algorithm assumes that the humidification chamber is holding 400 ml of water. If the chamber has less than 400 ml then the warm up time will take long r as the smaller amount of water will take less time to reach set temperature, causing the element duty cycle to settle to a lower level more quickly, resulting in a lower rate of net energy transfer ($E_{net} = E_{transferred} - E_{cond} -$

E_{conv}) to the water. In experimental conditions the warm up times for the humidified CPAP machine have varied between about 15 and 25 minutes depending on the operating conditions.

5 It should also be noted that in the above preferred embodiment, fan speed is essentially controlled dependent upon an indirectly determined water temperature. However, as has previously been explained, it is desirable to control the pressure of gases delivered to the patient dependent upon the humidity of those gases. The pressure (P) and flow rate (Q) in the above described system (approximately 6 foot hose length etc) can be approximated by the following equation:

10

$$P = 8.836 \times 10^{-3} Q^2$$

15 Accordingly, pressure increases with the square of fan speed. However, with the above equation it is possible to utilise fan speed as an indication of pressure and to calculate the gases pressure from it. Similarly, it would be possible to produce an equation relating temperature to humidity, for example, by determining the mass of water evaporating per second and dividing that value by the present flow. Therefore, although this preferred embodiment of the present invention has been described with reference to fan speed and temperature, the system still ensures that the gases pressure is controlled to deliver the patient with adequately humidified gases only. The known relationships between fan speed and pressure and temperature and humidity could also be used in the above described step 1 so that the user could input required pressure and humidity values directly to the device. Controller 9 could then calculate the required fan speed and temperature values and carry out the remaining steps accordingly.

20

25

The graphs shown in Figure 5 show that the heater plate temperature reaches its set temperature relatively quickly and that, due to the control system described above in relation to the second preferred embodiment, the fan speed (RPM in Figure 5) increases more gradually in line with the increase in water temperature.

30

Other Considerations

In cases where the heater plate temperature is near the set temperature at start up of the system (for example when the patient has been using the device but has been called away temporarily and switched the device off or placed the device into a standby mode), the controller may do away with keeping the temperature and pressure in step as they increase. In this case, the controller may first determine whether the actual heater plate temperature is about or greater than about 75% of its required set value or alternatively within say 5°C of its set value. If this is the case then the speed of fan 21 is controlled to linearly increase from some low initial value to the required set value over a predetermined period of time (for example 15 minutes). Alternatively, the controller could determine if the actual heater plate temperature is within a range, for example a range of about 10°C, of the required set temperature value and then control the speed of fan 21 to reach the set value of fan speed in a predetermined period of time

The above mentioned alternative steps are required due to the fact that as the heater plate is already warm it will soon reach its set temperature (before the patient has fallen asleep) and therefore the full fan speed should be delayed for a set period to allow the gases to be humidified within the capability of the humidifier to humidify the gases and/or to allow the user to achieve sleep before maximum flow rate occurs. The predetermined period of time could be set by the manufacturer prior to sale of the device or alternatively this value could be user controllable by for example adding a further dial and input to the controller 9.

The controller also preferably monitors the calculated net energy transfer value (E_{net}) and if it is found to be zero or negative (over for example a 30 second period), then it is decided that warmup must be complete (due to the fact that there was less energy needed from startup than was calculated due to there being less water in the chamber than expected). In this situation the fan speed is automatically increased to the set fan speed. Another feature could be the monitoring of the warmup period so that if warmup is still occurring after about 25 minutes, then the fan speed could be automatically increased to the set fan speed as the warmup period should have ended.

A further addition could be in the provision of a button with an input to controller 9. The button could be pressed by the user to commence the above fixed period of linear fan speed increase. Once the warm up has been completed

(temperature and pressure have reached their required values), the user may find that they have been unable to drift off to sleep and therefore they require the fan speed to be temporarily reduced. In this case, the user could simply repress the abovementioned button and another linear fan speed increase would occur (even though the water temperature would already be at its required set temperature) starting at a low predetermined speed and linearly increasing to the required set speed.

Accordingly, the present invention provides a humidified breathing assistance system in which the patient is provided with beneficially humidified gases during the period when the humidifier is warming up and also when the humidifier is running (and at its set temperature). In addition, the humidity of the gases supplied to the patient are maintained throughout both of these periods within the limits of the humidifiers ability to humidify those gases to the benefit of the patient. This is extremely beneficial to the patient as even a flow of non-humidified or insufficiently humidified gases to the patient for a short duration of time (for example 10 minutes) can cause detrimental swelling of the nasal passages and even greater discomfort if delivered orally.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Breathing assistance apparatus adapted to deliver gases to a patient to assist said patient's breathing comprising:

5 gases supply means, including pressure regulating means adapted to supply gases at a required pressure with a resulting gases flow rate,

gases pressure sensing means to determine the pressure of said supplied gases and thereby the resulting gases flow rate,

10 humidification means which receive and humidify said supplied gases prior to delivery to said patient, said humidification means capable of controllably humidifying said gases up to a required humidity level,

transportation pathway means which convey said humidified gases to said patient,

15 gases humidity sensing means to determine the humidity of the gases supplied to said patient, and

20 control means which in response to said gases humidity and said gases pressure and resultant flow rate information supplied by said gases humidity sensing means and said gases pressure sensing means, control said gases supply means such that said gases pressure and resultant flow rate reach said required pressure and resultant flow rate at substantially the same time as said gases humidity reaches required humidity.

25 2. Breathing assistance apparatus as claimed in claim 1 wherein said humidification means comprise a humidification chamber means adapted to receive a volume of water and an energisable heating means to heat said volume of water to produce water vapour within said humidification chamber means, said gases passing through said water vapour in said humidification chamber means thereby being humidified.

30 3. Breathing assistance apparatus as claimed in claim 1 or 2 wherein said pressure regulating means comprise a variable speed fan and said pressure sensing means comprise a speed sensor which senses the speed of said fan to provide said control means with an indication of the flow rate of said gases flow.

4. Breathing assistance apparatus as claimed in claim 2 or 3 wherein said gases humidity sensing means are part of said control means and include a means to sense the temperature of said energisable heating means wherein the humidity of said gases is estimated based on said sensed temperature of said energisable heating means.

5. Breathing assistance apparatus as claimed in claim 2 or 3 wherein said gases humidity sensing means are part of said control means and include a means to sense the temperature of said energisable heating means wherein the humidity of said gases is estimated based on a calculated value for the temperature of said volume of water within said humidification means, said calculated temperature value determined by adding an amount dependent upon the amount of energy which has been added to said volume of water to said sensed temperature of said energisable heating means.

6. Breathing assistance apparatus as claimed in any one of claims 1 to 5 wherein said control means is a programmable processor which stores a program which when executed in said processor carries out the steps of:

i) determining the total amount of energy required to be transferred to said humidification means to reach said required humidity level,

ii) determining the present rate of energy transfer to said humidification means,

iii) calculating a time to reach said required humidity level by dividing said total amount of energy required determined in step (i) by said rate of energy transfer determined in step (ii), and

iv) controlling said pressure regulating means to deliver said gases from said gases supply means at a pressure which is substantially similar in proportion to said required pressure as said humidity of said gases is to said required humidity level,

wherein steps (i) to (iv) are repeated until said supplied gases are substantially humidified to said required humidity level and are at substantially said required pressure and resultant flow rate.

7. Breathing assistance apparatus as claimed in claim 6 wherein said rate of energy transfer in said step (ii) is estimated by determining the amount of energy transferred

to said humidification means during a predetermined period of time and dividing said determined amount of energy by said predetermined period of time.

5 8. Breathing assistance apparatus as claimed in claim 7 wherein a first amount equal to the estimated convection energy losses in said breathing assistance apparatus and a second amount equal to the estimated conduction energy losses in said breathing assistance apparatus, are added to said determined amount to calculate said time to reach said required humidity level in step (iii).

10 9. Breathing assistance apparatus as claimed in any one of claims 6 or 8 wherein a first amount equal to the estimated convection energy losses in said breathing assistance apparatus and a second amount equal to the estimated conduction energy losses in said breathing assistance apparatus, are subtracted from said total amount of energy transferred to said humidification means to calculate said time to reach said
15 required humidity level in step (iii).

10. Breathing assistance apparatus as claimed in any one of claims 7 to 9 wherein said predetermined period of time is about 30 seconds.

20 11. Breathing assistance apparatus as claimed in any one of claims 6 to 10 wherein said step (i) involves calculating an initial amount of energy required and subtracting the amount of energy subsequently transferred to said humidifying means in the accumulated preceding predetermined periods of time.

25 12. Breathing assistance apparatus as claimed in any one of claims 1 to 11 wherein said transportation pathway means contain therein a pathway heating means which are adapted to be controllably energised by said control means to reduce condensation along the length of said transportation pathway means.

30 13. Breathing assistance apparatus as claimed in any one of claims 1 to 12 which further comprise a variable user input means which in response to an input from an

operator causes said control means to control said gases supply means to achieve a predetermined pressure profile of said supplied gases independent of said humidity of said gases for a period of time determined by said input of said operator.

5 14. Breathing assistance apparatus as claimed in claim 13 wherein said predetermined pressure profile is a linear ramp up of said supplied gases from an initial lower pressure to a final pressure equal to said required pressure.

10 15. A method of operating patient breathing assistance apparatus, said breathing assistance apparatus comprising gases supply means, gases pressure regulating means adapted to supply gases at a required pressure with a resulting gases flow rate, gases humidification means capable of controllably humidifying said gases up to a required humidity level, transportation means which channel said humidified gases to said patient and control means storing predetermined required pressure and humidity values,
15 said method comprising the steps of:

a) initiating said gases humidification means to humidify the gases from said gases supply means,

b) sensing the pressure of said gases,

c) sensing the humidity of said gases, and

20 d) controlling the pressure at which said gases are supplied to said patient so that said gases pressure and resultant flow rate reach said required pressure and resultant flow rate at substantially the same time as said required humidity level is reached.

25 16. A method as claimed in claim 15 wherein said humidification means comprise a humidification chamber means adapted to receive a volume of water and an energisable heating means to heat said volume of water to produce water vapour within said humidification chamber means, said gases passing through said water vapour in said humidification chamber means thereby being humidified.

30 17. A method as claimed in claims 15 or 16 wherein said pressure regulating means comprise a variable speed fan and said step of sensing the pressure and resultant flow

rate of said gases comprises the step of sensing the speed of said fan to provide said control means with an indication of the pressure and resultant flow rate of said gases flow.

5 18. A method as claimed in claim 16 or 17 wherein said step of sensing the humidity of said gases comprises estimating the humidity based on the temperature of said energisable heating means.

10 19. A method as claimed in claim 16 or 17 wherein said step of sensing the humidity of said gases comprises estimating the humidity based on a calculated value for the temperature of said volume of water within said humidification means, said calculated temperature value determined by sensing the temperature of said energisable heating means and adding to that an amount dependent upon the amount of energy which has been added to said volume of water.

15 20. A method as claimed in any one of claims 15 to 19 wherein step (d) further comprises the steps of:

20 1) determining the total amount of energy required to be transferred to said humidification means (8) for said gases humidity to reach said required humidity level,

2) determining the rate of energy being transferred to said humidification means,

3) calculating a time to reach said required humidity level by dividing said total amount of energy required determined in step (1) by the rate of energy transfer determined in step (2),

25 4) controlling said pressure regulating means to deliver said gases from said gases supply means at a pressure which is substantially similar in proportion to said required pressure as said humidity of said gases is to said required humidity level

and wherein steps (1) - (4) are repeated until said supplied gases are substantially humidified to said required humidity level at substantially said required pressure level and resultant gas s flow rate.

30 21. A method as claimed in claim 20 wherein said step (2) involves determining the

amount energy transferred to said humidification means in a predetermined period of time and dividing said determined amount of energy by said predetermined period of time.

5 22. A method as claimed in claim 21 wherein a first amount equal to the estimated convection energy losses in said breathing assistance apparatus and a second amount equal to the estimated conduction energy losses in said breathing assistance apparatus, are added to said determined amount to calculate said time to reach said required humidity level in step (3).

10 23. A method as claimed in any one of claims 20 to 22 wherein a first amount equal to the estimated convection energy losses in said breathing assistance apparatus and a second amount equal to the estimated conduction energy losses in said breathing assistance apparatus, are subtracted from said total amount of energy transferred to said
15 humidification means to calculate said time to reach said required humidity level in step (3).

20 24. A method as claimed in any one of claims 21 to 23 wherein said predetermined period of time is about 30 seconds.

25 25. A method as claimed in any one of claims 20 to 24 wherein said step (1) involves calculating an initial amount of energy required and subtracting the amount of energy subsequently added to said humidifying means in the accumulated preceding predetermined periods of time.

30 26. A method as claimed in any one of claims 15 to 25 wherein a pathway heating means contain within said transportation pathway means is controllably energised by said control means to reduce condensation along the length of said transportation pathway means.

27. A method as claimed in any one of claims 15 to 26 wherein said breathing

assistance apparatus further comprise a variable user input means, and wherein said control means controls said gases supply means to achieve a predetermined pressure profile of said supplied gases independent of said humidity of said gases for a period of time in response to an input from an operator, where said predetermined time being
5 determined by said input of said operator.

28. A method as claimed in claim 27 wherein said predetermined pressure profile is a linear ramp up of said supplied gases from an initial lower pressure to a final pressure equal to said required pressure.

10 29. A method for treating Obstructive Sleep Apnea in a patient using a breathing assistance apparatus comprising gases supply means, gases pressure regulating means adapted to supply gases at a required pressure with a resulting gases flow rate, gases humidification means capable of controllably humidifying said gases up to a required
15 humidity level, transportation means which convey said humidified gases to said patient and control means storing predetermined required pressure and humidity values, said method comprising the steps of:

A) initiating said gases humidification means to humidify the gases from said gases supply means,

20 B) sensing the pressure of said gases,

C) sensing the humidity of said gases, and

D) controlling the pressure at which said gases are supplied to said patient so that said gases pressure and resultant flow rate reaches said required pressure and resultant flow rate at substantially the same time as said required humidity level is reached.

25 30. A method for treating Obstructive Sleep Apnea as claimed in claim 29 wherein step (D) further comprises the steps of:

I) determining the total amount of energy required to be transferred to said humidification means (8) for said gases humidity to reach said required humidity level,

30 II) determining the rate of energy being transferred to said humidification means,

III) calculating a time to reach said required humidity level by dividing said total

amount of energy required determined in step (I) by the rate of energy transfer determined in step (II),

5 IV) controlling said pressure regulating means to deliver said gases from said gases supply means at a pressure which is substantially similar in proportion to said required pressure as said humidity of said gases is to said required humidity level

and wherein steps (I) - (IV) are repeated until said supplied gases are substantially humidified to said required humidity level at substantially said required pressure level and resultant gases flow rate.

10 31. Breathing assistance apparatus substantially as herein described with reference to and as illustrated by the accompanying drawings.

32. A method substantially as herein described with reference to and as illustrated by the accompanying drawings.

15

33. A method for treating Obstructive Sleep Apnea substantially as herein described with reference to and as illustrated by the accompanying drawings.

20



Application N : GB 9914080.8
Claims searched: 1-28 and 31

Examiner: Anwar Gilani
Date of search: 12 October 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): A5T (TDB)

Int Cl (Ed.6): A61M 16/16

Other: Online: WPI, EPODOC, JAPIO

Documents considered to be relevant:

| Category | Identity of document and relevant passage | Relevant to claims |
|----------|---|---------------------------|
| X, Y | EP0845277 A1 (FISHER & PAYKEL) whole document | X: 1-5 and 15-19 Y: 12 |
| X | US5349946 (McCOMB) col. 3 l. 7-col. 4 l. 14 | 1 at least |
| Y | US5163423 (SUZUKI) col. 1 l. 40-48 | 12 |

| | | | |
|---|---|---|--|
| X | Document indicating lack of novelty or inventive step | A | Document indicating technological background and/or state of the art |
| Y | Document indicating lack of inventive step if combined with one or more other documents of same category. | P | Document published on or after the declared priority date but before the filing date of this invention. |
| & | Member of the same patent family | E | Patent document published on or after, but with priority date earlier than, the filing date of this application. |